Components Sample Table 1

Definition of Component:

A component is a full consortium member of a MBCCOP. A consortium agreement (letter) between the MBCCOP organization and each component must be included in the application. OHRP assurance requirements must be met (see MBCCOP RFA, Section VI. 2. A. Cooperative Agreement Terms and Conditions of Award, 2.A.1. MBCCOP Awardees Responsibilities <u>Federally Mandated</u> Requirements).

**Directions:** Colum

- Column (2) Indicate if component is a hospital, group/office practice, or other organization (indicate type). If hospital, indicate all applicable codes: 1=Not for Profit; 2=Federal Government (VA or MTF); 3=For Profit; 4=State/County/City Government; 5=Teaching 6=Medical School; 7=Approved Residency; 8=Formal Medical Affiliation with Student Rotation.
  - (3) Indicate if hospital has a current American College of Surgeons (ACOS) accredited cancer program.
  - (5) Use new cases diagnosed or receiving primary treatment at that hospital or physicians group, practice except for basal cell or squamous cell carcinoma of the skin.
  - (6) Indicate OHRP FWA number.

(1) Name of Component	Des	(2) scription				5) r of New	(6)
Name of Component Address Telephone Number	H=Hospital G=Group O=Other	If Hospital enter applicable codes (see above)	Accredited Program Yes/No	of Hospital Beds (Hospital Only) 2006		Patients patient) 2005	OHRP Assurance Number

Affiliates Sample Table 2

Definition of Affiliate:

Occasionally, a MBCCOP may want to establish a relationship with an organization that may be able to put a minimum number of patients on protocols but for which full consortium membership is not appropriate. OHRP assurance requirements must be met (see MBCCOP RFA Section VI. 2. A. Cooperative Agreement Terms and Conditions of Award, 2.A.1. MBCCOP Awardees Responsibilities Federally Mandated Requirements).

Directions: Column (2)

- (2) Indicate if affiliate is a hospital, group/office practice, or other organization (indicate type). If hospital, indicate all applicable codes: 1=Not for Profit; 2=Federal Government (VA or MTF); 3=For Profit; 4=State/County/City Government; 5=Teaching 6=Medical School; 7=Approved Residency; 8=Formal Medical Affiliation with Student Rotation.
- (3) Indicate if hospital has a current American College of Surgeons (ACOS) accredited cancer program.
- (5) Use new cases diagnosed or receiving primary treatment at that hospital or physicians group, practice except for basal cell or squamous cell carcinoma of the skin.
- (6) Indicate OHRP FWA number.

(1)	Des	(2) scription	(3) (4) ACOS Total Number		(5) Number of New		(6) OHRP
Name of Affiliate Address Telephone Number	H=Hospital G=Group O=Other	If Hospital enter applicable codes (see above)	Accredited Program Yes/No	of Hospital Beds (Hospital Only) 2006		Patients patient) 2005	Assurance Number

Column:

- (1) Group by component/affiliate with which physician is affiliated. If a physician is affiliated with multiple components, list him/her only with primary component.
- (2) List all physicians who will participate in your MBCCOP, then indicate:
- (3) Type of practice: Group=G; Solo=S; or Hospital-Based =H.
- (4) Type of participation: enter "A" if the physician is expected to enter patients on NCI-approved clinical trials or "B" if the physician will be aware of trial requirements and actively support the MBCCOP but will not be actually registering patients (e.g., a pathologist or a diagnostic radiologist).
- (5 Physician's year of graduation from medical school.
- (6) Physician's specialty/subspecialty.
- (7) Indicate whether physician is board-certified or board-eligible for specialty.

(1)	(2)	(3) (4) (5) Practice Type Type Partic. Grad.	(6)	(7) Board			
Component/ Affiliate	Physician's Full Name	Type G/S/H	Partic. A/B	Grad. Year	Specialty/ Subspecialty	Cert.	Elig.

Column:

- (1) Group by component/affiliate with which individual is affiliated. If an individual is affiliated with multiple components, list him/her only with primary component.
- (2) List all non-physician investigators responsible for patients/participants on cancer prevention and control trials in your MBCCOP.
- (3) List highest degree attained.
- (4) Enter the year the highest degree was confirmed.
- (5) Individual's specialty/discipline.

(1)	(2)	(3)	(4)	(5)
Component/ Affiliate	Individual's Full Name	Highest Degree	Year Degree Confirmed	Specialty/ Discipline

List all personnel (e.g., MBCCOP administrator/coordinator, clinical research associates, data managers, nurses) who will participate in the MBCCOP activities. Indicate MBCCOP component/affiliate with which person is most closely associated. Please complete all columns.

(1) Component/Affiliate	(2) Individual's Full Name	(3) Check if R.N.	(4) Highest Academic Degree	(5) Position	(6) Proposed Hrs/Week on MBCCOP Activities

Directions:	Provide figures for the table below to the extent possible. Use new cases diagnosed or receiving treatment at that hospital, except for basal cell or squamous cell carcinoma of the skin. Submit a separate sheet for each hospital component.
Name of Component:	
Information Source:	<ul> <li>☐ Hospital Registry</li> <li>☐ Hospital Registry</li> <li>☐ Hospital Discharge Data</li> <li>☐ Other</li> </ul>

	Calendar Year 2004 2005		Calendar Year 2004 2005
Breast Tumor		Non-Small Cell Lung	
Esophagus		Hodgkin=s Disease	
Stomach		Non-Hodgkin=s Disease	
Pancreas		Kaposi=s Sarcoma	
Hepatobiliary		Melanoma	
Colon		Head/Neck Tumors	
Rectum		Brain/Other CNS Tumors	
GI (other)		Endocrine	
Bladder		Osteogenic Sarcoma	
Kidney		Soft Tissue Sarcoma	
Prostate		Rhabdomyosaracoma	
Testis		Ewing=s Sarcoma	
GU (other)		Sarcoma (other)	
Cervix		Wilm=s Tumor	
Ovary		Neuroblastoma	
Uterus, Endometrial		Pediatric ALL	
GYN (other)		Pediatric AML	
Myeloma		Pediatric Acute Leukemia (other)	
Adult Acute Lymphocytic		Pediatric Lymphomas incl. Hodgkin=s Disease	
Adult Acute Non-Lymphocytic		Pediatric Solid Tumors/Others	
Chronic Leukemia		Other	
Small Cell Lung			

Total:

Column:

- (1) Indicate if currently participating in MBCCOP (Yes or No).
- (3) Indicate trial source: name of cooperative group or cancer center.
- (4) Code the accrual by predominant practice mode for a given year: private practice = P; salaried academic = A; training/fellowship = F.

This table is intended to reflect current entries and is not a substitution for the total treatment accrual in the progress report (if applicable). For all current and projected physicians, please list accrual by physician to all NCI-approved trials (e.g.: Cooperative Group/Cancer Center Research Bases).

(1) Names of Existing MBCCOP Physicians* and Proposed Participating Physicians	(2) MBCCOP Phys. (Y/N)	(3) Trial Source	Numbe	(4) er of Patients E 6/04-5/05	Entered 6/05-5/06
Example: Jane R. Doe, MD	Y	NSABP	0/F	13/F	20/A
	l				
Page Totals:					
Existing MBCCOP Physicians:*					
All Physicians:					
Grand totals (last page only):					
Existing MBCCOP Physicians					
All Physicians:					

\* Applies to continuing applicant only

Narrative explanation may be attached if needed to fully document your experience.

Column

- (2) Indicate if currently participating in MBCCOP (Yes or No).
- (3) Indicate trial source: may be single institution studies, drug companies, local hospitals, or others.
- (4) Code accrual by predominant practice mode for given year: private practice = P; salaried academic = A; training/fellowship = F.

For all current and projected physicians, please list accrual by physician to all other trials (e.g.: pharmaceutical studies, etc.)

(1) Names of Existing MBCCOP Physicians* and	(2) MBCC OP	(3)	(4) Number of Patients Entered					
Proposed Participating Physicians	Phys. (Y/N)	Trial Source	6/03-5/04	6/04-5/05	6/05-5/06			
Example: Jane R. Doe, MD	Υ	Eli Lilly	0/F	5/F	10/A			
Page Totals:			<u> </u>					
Existing MBCCOP Physicians:* All Physicians:								
Grand totals (last page only):								
Existing MBCCOP Physicians			_	<del>-</del>	_			
All Physicians:								

Applies to continuing applicant only

Narrative explanation may be attached if needed to fully document your experience.

Column (2) Indicate if currently participating in MBCCOP (Yes or No).

- (3) Indicate trial source: name of cooperative group; cancer center; other organization
- (4) Code the accrual by predominant practice mode for a given year: private practice = P; salaried academic = A; training/fellowship = F.

This table is intended to reflect current and proposed entries and is not a substitution for the total cancer prevention/control accrual in the progress report (if applicable). For all current and projected physicians, please list accrual by physician to all NCI approved trials (e.g.: Cooperative Group/Cancer Center Research Base protocols).

(1) Names of Existing	(2)	(3)	Numb	(4) er of Participants	Entered
MBCCOP Physicians* and Proposed Participating Physicians	MBCCOP Phys. (Y/N)	Trial Source	6/03-5/04	6/04-5/05	6/05-5/06
Example: Jane R. Doe, MD	Υ	NSABP	0/F	13/F	20/A
Page Totals:	•			•	
Existing MBCCOP Physicians:*					
All Physicians:					
Grand totals (last page only):					
Existing MBCCOP Physicians:					
All Physicians:					

Narrative explanation may be attached if needed to fully document your experience.

<sup>\*</sup> Applies to continuing applicant only

Directions: Information to be provided as part of the Progress Report (for prior funding period of up to 5 years) for applicants submitting competing continuation applications.

Column (1) Indicate trial source: name of CCOP Research Base.

(2) Indicate the total number of patients and the credit equivalent (see <a href="http://www.nci.nih.gov/prevention/ccop/protodev.html#credit">http://www.nci.nih.gov/prevention/ccop/protodev.html#credit</a>) entered onto NCI approved cancer treatment clinical trials.

(1)		(2) Number of Patients - Credits								
ССОР	6/01 -	- 5/02	6/02 -	5/03	6/03 -	5/04	6/04 -	5/05	6/05 -	5/06
Research Base	Patients	Credits	Patients	Credits	Patients	Credits	Patients	Credits	Patients	Credits
Example: SWOG	63	63	75	75	60	55	80	80	75	70

Narrative explanation may be attached if needed to fully document your experience.

Directions: Information to be provided as part of the Progress Report (for prior funding period of up to 5 years) for applicants submitting competing continuation applications.

Column (1) Indicate trial source: name of CCOP Research Base.

Indicate the total number of new entry credits & follow-up (FU) credits (see <a href="http://www.nci.nih.gov/prevention/ccop/protodev.html#credit">http://www.nci.nih.gov/prevention/ccop/protodev.html#credit</a>) for accrual to NCI approved cancer prevention/control clinical trials.

## **Special Instruction:**

Please list the Breast Cancer Prevention Trial (BCPT), the Prostate Cancer Prevention Trial (PCPT)), the Study of Tamoxifen and Raloxifene (STAR) and the Selenium and Vitamin E Trial in Prostate Cancer Prevention (SELECT) on separate lines.

(1)		(2) New Entry Credits & Follow-up Credits								
CCOP Research Base	6/01 -	5/02	6/02 -	6/02 - 5/03 6/03		5/04	6/04 - 5/05		6/05 - 5/06	
	New Entry Credits	FU Credits	New Entry Credits	FU Credits	New Entry Credits	FU Credit	New Entry Credits	FU Credits	New Entry Credits	FU Credits
Example: SWOG	20	0	10	0	25	0	10	0	15	1
Example: STAR (NSABP P-2)	20	0	30	6	30	15	25	24	0	31.5
Total Table 7B:										
Total Credits/Year (New & FU):										

Narrative explanation may be attached if needed to fully document your experience.

NCI 04/2006

See MBCCOP RFA, Section VI. 2. A. Cooperative Agreement Terms and Conditions of Award, 2.A.1. Part A. MBCCOP Awardee Responsibilities, Affiliations of MBCCOP Awardees with Research Bases

Name of Research Base	Name & Location of Intermediary Institution, if Applicable	Treatment Research Yes/No	Cancer Prevention and Control Research Yes/No

In the narrative, describe previous working relationships with proposed Research Base, if applicable. Include information on committee memberships and chairmanships as well as studies chaired. If one or more components participated as cooperative group affiliate program satellite hospitals, specify the years.

Limit to two pages.

This table should reflect the entire anticipated MBCCOP treatment accrual for the coming year.					
(1)	(2)	(3)	(4) Anticipated Patient Accrual		
Title	NCI Protocol Number	Disease Site	Patients Available	Patients to be Placed on Study	Accrual Credits <sup>1</sup>
Subtotal for Research Base:					
		Grand Total (last pa	age only):		

<sup>&</sup>lt;sup>1</sup> For information on credit see: <a href="http://www.nci.nih.gov/prevention/ccop/protodev.html#credit">http://www.nci.nih.gov/prevention/ccop/protodev.html#credit</a>

Projected Accrual to NCI Approve	d Cancer Prevention/Cor	ntrol Clinical Trials	during the Next Yea	r Sample	Table 9B
Directions: Organize by Re	search Base(s). Use se <sub>l</sub>	parate page(s) for e	ach Research Base.		
Name of Research Base:					
This table should reflect the entire	e anticipated MBCCOP p	revention and conti	ol accrual for the co	oming year.	
(1)	(2)	(3)	(4) Anticipated Participants Accrual		
Title	NCI Protocol Number	Disease Site	Participants Available	Participants to be Placed on Study	Accrual Credits <sup>1</sup>
	+			+	

Subtotal for Research Base:	
Grand Total (last page only):	 

 $<sup>^{1}</sup> For \ information \ on \ credit \ see: \ \underline{http://www.nci.nih.gov/prevention/ccop/protodev.html\#credit}$